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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,946	09/29/2003	Ashish Varma	PA1436	8308

28390 7590 03/24/2008

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1797	

NOTIFICATION DATE	DELIVERY MODE
03/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/671,946	VARMA ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-13,15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-13,15 and 17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 7-13, and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2003/0083616) in view of Ahlqvist et al. (US 5,881,534) and Columbo (US 6,520,323).

With respect to claims 1-3, 7-13, 17, and 20-24, Lee et al. teaches a method of sterilizing a catheter balloon susceptible to degradation by ionizing radiation. The balloons are fabricated from polyether block amides (PEBAX). In the method of Lee et al., the balloon is packaged in the sealed interior space of a package **32** capable of providing a barrier to atmospheric oxygen wherein the package includes a first layer including a plastics coated foil and a porous second layer (paragraph [0026]). The balloon and the package are evacuated down to 50 mTorr to remove all air and oxygen from the balloon and package and the package backfilled with nitrogen. See paragraphs [0008-0009]. The level of vacuum disclosed by Lee et al. in combination with the nitrogen flush would have intrinsically been capable of reducing the oxygen content to the level claimed. To sterilize the balloon, the balloon within the container is exposed to electron beam radiation at a dose of 3-10 Mrad (30-100 kGy). See paragraph [0024]. Lee et al. is silent with respect to placing an oxygen absorber in a second sealed space within the package.

Ahlqvist et al. discloses a method of sterilization of sensitive polymeric medical devices wherein the devices are placed within sealed packages along with an oxygen absorber (contained within a second sealed interior space) and irradiated with electron beam radiation. See col.6, line 48 to col.7, line 21. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the oxygen absorbing sachet of Ahlqvist et al. within the sealed package of Lee et al. in order to assure low-oxygen conditions of the sealed package during extended periods of storage, as taught by Ahlqvist et al.. In the invention of Ahlqvist et al., the second sealed interior space is not formed by a seal line attaching at least one of the first layer and second layer to itself. Instead, it is a small bag employed to hold the oxygen absorber.

Nevertheless, Columbo evidences that it was known in the art at the time of the invention to contain place an article to be protected within a first sealed interior space **104** and an oxygen absorbing composition within a second sealed interior space **102**, wherein the second sealed interior space is formed by a seal line **111** attaching at least a layer of the packaging material to itself. See col.8, line 64 to col.9, line 62, especially col.9, lines 59-61. It would have been obvious to one of ordinary skill in the art at the time of the invention to contain the oxygen absorbing composition and the polymeric medical device of the combination in the manner disclosed by Columbo, as being a functional equivalent of the method disclosed by Ahlqvist et al.. The results of using unitary packaging, in the manner of Columbo, for that of the combination would have been readily apparent and certainly expected to one of ordinary skill in the art.

As to claims 18 and 19, Lee et al. is silent to the use of gamma radiation as the energy source. However, Ahlqvist et al. discloses that both electron beam and gamma radiation were

known in the art at the time of the invention for the sterilization of polymeric medical articles. See col.1, lines 19-28. Furthermore, Ahlqvist et al. teaches applying the gamma radiation to the articles at a dose rate of 0.1 Mrad/hr (1 kGy/hr). See col.7, lines 33-36. It would have been obvious to one of ordinary skill in the art to employ gamma radiation as the energy source in the method of Lee et al. since Ahlqvist et al. teaches that they are functional equivalents in the art of polymeric medical article sterilization. Moreover, it would have been obvious to choose the dose rate disclosed by Ahlqvist et al. as it has been shown to be safe and effective in the sterilization of sensitive medical articles.

3. Claims 5, 15, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. and Ahlqvist et al. as applied to claims 1, 11, and 24 above, and further in view of George (US 5,014,494).

Lee et al. with Ahlqvist et al. is silent with respect to the particular packaging materials claimed. George teaches a similar method of sterilizing sensitive polymeric medical materials within sealed packages. The package material is preferably a multilayer material with polymeric layers and an aluminum layer. Other known package materials are disclosed, including peelable laminates. As the materials in the claimed layers are conventional in the art of packaging for sterilization with ionizing radiation, it would have been obvious to one of ordinary skill in the art to arrange the layers of the multilayer packaging in any configuration, absent any showing of unexpected results.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/
Primary Examiner, Art Unit 1797

elm
16 March 2008